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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/551,151	04/14/2000	Thor Borgford	10447-011	1104

1059 7590 11/04/2003

BERESKIN AND PARR  
SCOTIA PLAZA  
40 KING STREET WEST-SUITE 4000 BOX 401  
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CANADA

EXAMINER

LIU, SAMUEL W

ART UNIT PAPER NUMBER

1653

DATE MAILED: 11/04/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 09/551,151	<b>Applicant(s)</b> BORGFORD, THOR	
	<b>Examiner</b> Samuel W Liu	<b>Art Unit</b> 1653	

-- The MAILING DATE of this communication appears on the cover sheet with the corresponding address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 17 September 2003.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 40,45,49,51,55,57 and 58 is/are pending in the application.
- 4a) Of the above claim(s) none is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 40,45,49,51,55,57 and 58 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

### Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                  | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____  |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)         | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____                                    |

## DETAILED ACTION

### *Status of the current Application*

Applicant's response filed 17 September 2003 which amends claims 40, 49-50, 55 and 57, and cancels claims 41-44, 46-48, 50, 52-54 and 56 have been entered. Claims 40, 45, 49, 51, 55 and 57-58 are pending. The following Office Action is applicable to the pending claims 40, 45, 49, 51, 55 and 57-58. Note that claims 1-39 are previously cancelled by applicants (see the amendment filed 28 April 2003).

Please note that rejections not explicitly stated and/or restated below are also withdrawn.

*The following rejection is maintained in view of the applicants' amendment of the claims.*

### *Objection to claims*

Claims 55 and 57 are objected to as being dependent upon a rejected base claim (i.e., claim 40, see below), but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

### *Claim Rejections - 35 USC § 102*

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 40 is rejected under 35 U.S.C. 102 (b) as being anticipated by Westby, M. et al. (*Bioconj. Chem.* (1992) 3, 375-381) as is evidenced by the known fact disclosed in the reference (Sampson, M. T. et al. (2003) *Biochem. Society Trans.* Vol. 30, part 2, pages 201-207).

Westby et al. teach a recombinant protein comprising ricin A, ricin B and a linker sequence between ricin sequences A and B, wherein the linker comprises a trypsin-sensitive sequence (substrate of Factor Xa enzyme) for cleaving continuity between ricin A and ricin B (see abstract, page 375, and Figure 1), wherein the factor Xa is a cancer associate protease which characteristic is inherent as is evidenced by Sampson et al. reference. Thus, the Westby et al. teaching anticipates claim 40 of the instant application.

Response to the rejection under 35 USC 102

The response filed 17 September 2003 asserts that Westby et al. reference is not an anticipatory art because Westby et al. do not teach the use of proricin in the treatment of diseased cells and that claim 40 has been amended to be directed to the recombinant protein comprising ricin A/B and a linker containing a cleavage site for cancer associated protease which would obviate the rejection (see page 26, the first paragraph).

The applicants' argument is found unpersuasive because of the following reasons. (i) Factor Xa is a cancer-associated protease as is evidenced by Sampson et al.; thus, the characteristic of the cleavage site of the reference is inherent. (ii) When a claim recites using an old composition or structure (e.g., factor Xa enzyme) and the use is directed to a result or property of that composition or structure (e.g., cleavage of the factor Xa site that resides in the linker sequence) then the claim is anticipated. See MPEP 2112.02. Also, see Bristol-Myers Squibb Co. v. Ben Venue Laboratories, Inc. 58 USPQ2d 1508 (CA FC 2001); Ex parte Novitski 26 USPQ 1389 (BPAI 1993); Mehl/Biophile International Corp. V. Milgraum, 52 USPQ2d 1303 (Fed. Cir. 1999); Atlas Powder Co. V. IRECO, 51 USPQ2d 1943 (Fed. Cir. 1999). (iii) claim 40 is directed to product not a use of the product thereof; use of the product will NOT alter

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structural and biochemical property of the product. Therefore, irrespective of how to use of the claimed ricin polypeptide in treating diseased cells, the Westby et al. reference anticipates the claimed subject matter.

*Claim Rejection –Obviousness Type Double Patenting over US Pat. No. 6531125 is withdrawn in view of applicants' amendment of the claims of the current application.*

*The following rejection is maintained because applicants do not respond to the rejection.*

***Provisional Rejection - Obviousness Type Double Patenting***

Claims 40, 45, 49, 51 and 58 of this application conflict with claims 15, 17, 22, 26 and 40 of Application No. 10394511. 37 CFR 1.78(b) provides that when two or more applications filed by the same applicant contain conflicting claims, elimination of such claims from all but one application may be required in the absence of good and sufficient reason for their retention during pendency in more than one application. Applicant is required to either cancel the conflicting claims from all but one application or maintain a clear line of demarcation between the applications. See MPEP § 822.

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130 (b). Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 40, 45, 49, 51 and 58 are provisionally rejected under the judicially created doctrine of double patenting over claims 15, 17, 22, 26 and 40 of copending Application No. 09674266. This is a provisional double patenting rejection because the conflicting claims have not in fact been patented.

The subject matter claimed in the instant application is fully disclosed in the referenced copending application and would be covered by any patent granted on that copending application since the referenced copending application and the instant application are claiming common subject matter, as follows:

Claims 15 and 17 of Application 10394511 disclose a recombinant protein comprising A and B chains of a ricin-like toxin and a linker peptide sequence that comprises a protease cleavage site, wherein the protease is a cancer protease. Thus, claims 15 and 17 disclose the common subject matter of claim 40 of the instant application.

Claims 26 and 40 of Application 10394511 disclose the common subject matter of claims 49 and 58 of the instant application, respectively.

Claim 22 of Application 10394511 discloses that the above-mentioned cleavage site is matrix metalloproteinase specific, which is the obvious variation of claims 45 and 51 of the current application.

Therefore, the instant application and Application No. 10394511 claims are obvious variations, and they are not patentably distinct from each other.

It is noted that page 28 of the response filed 17 September 2003 requests abeyance of the obvious-type double patenting rejection until allowable subject matter is indicated. Note that no allowable subject matter can be indicated with a standing ground of rejection. Thus, it is suggested that applicant file the appropriate terminal disclaimer.

### ***Conclusion***

No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a).

Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Samuel Wei Liu whose telephone number is (703) 306-3483. The examiner can normally be reached from 9:00 a.m. to 5:30 p.m. on weekdays. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Christopher Low, can be reached on 703-308-2923. The fax phone number for the organization where this application or proceeding is assigned is 703 308-4242 or 703 872-9306 (official) or 703 872-9307 (after final). Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703 305-4700.



Samuel Wei Liu, Ph.D.

October 15, 2003



KAREN COCHRANE CARLSON, PH.D.  
PRIMARY EXAMINER